**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

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| SELWYN KARP, Individually and On Behalf of All Others Similarly Situated,<br><br>Plaintiff,<br><br>v.<br><br>VOYAGER THERAPEUTICS, INC., STEVEN M. PAUL, G. ANDRE TURENNE, JANE HENDERSON, ALLISON DORVAL, DINAH SAH, and OMAR KHWAJA,<br><br>Defendants. | Civ. A. No.<br><br>**CLASS ACTION COMPLAINT**<br><br>**COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**<br><br>JURY TRIAL DEMANDED |

Plaintiff Selwyn Karp ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Voyager Therapeutics, Inc. ("Voyager" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Voyager securities between June 1, 2017 and November 9, 2020, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Voyager, a clinical-stage gene therapy company, focuses on the development of treatments for patients suffering from severe neurological diseases. Included in the Company's preclinical programs is VY-HTT01 for Huntington's Disease. Voyager represent that VY-HTT01 is intended to work by knocking down HTT expression in neurons and astrocytes in the striatum and cortex (discrete regions in the brain that can be targeted with adeno-associated virus ("AAV")

gene therapy delivered directly into the brain), thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms.

3. On June 1, 2017, Voyager issued a press release announcing that it had selected VY-HTT01 as a lead clinical candidate for the treatment of Huntington's disease. The press release also indicated that, "[p]reclinical pharmacology and toxicology studies [were] underway with VY-HTT01 to support filing of an investigational new drug (IND) application in 2018."

4. In September 2020, Voyager submitted an investigational new drug ("IND") application for VY-HTT01 for the treatment of Huntington's disease to the U.S. Food and Drug Administration ("FDA").

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's VY-HTT01 IND submission to the FDA lacked key information regarding certain chemistry, manufacturing and controls ("CMC") matters, including, *inter alia*, drug-device compatibility and drug substance and product characterization; (ii) the Company's IND submission for VY-HTT01 was therefore deficient; (iii) the Company had thus materially overstated the likelihood of FDA approval for VY-HTT01 based on the IND submission; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

6. On October 12, 2020, Voyager issued a press release disclosing that it "has received feedback from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug (IND) submission for VY-HTT01 for the treatment of Huntington's disease." Specifically,

Voyager advised investors that it "has been notified that the IND was placed on clinical hold pending the resolution of certain chemistry, manufacturing and controls (CMC) matters."

7. Then, on November 9, 2020, Voyager issued a press release announcing the Company's third quarter 2020 financial results and corporate updates. In the press release, the Company disclosed that, with respect to its IND application for VY-HTT01, "Voyager recently received written feedback from the FDA requesting additional information on specific CMC topics, including drug-device compatibility and drug substance and product characterization."

8. On this news, Voyager's stock price fell $2.60 per share, or 23.21%, to close at $8.60 per share on November 10, 2020.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## JURISDICTION AND VENUE

10. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

12. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Pursuant to Voyager's most recent quarterly report on Form 10-Q, as of November 4, 2020, there were 37,465,777 shares of the Company's common stock outstanding. Voyager's common stock trades on the Nasdaq Global Select Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in

Voyager's common stock located within the U.S., some of whom undoubtedly reside in this Judicial District.

13. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## PARTIES

14. Plaintiff, as set forth in the attached Certification, acquired Voyager securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

15. Defendant Voyager, a clinical-stage gene therapy company, focuses on the development of treatments for patients suffering from severe neurological diseases. The Company was founded in 2013 and is headquartered in Cambridge, Massachusetts. Voyager's securities trade on the NASDAQ under the ticker symbol "VYGR."

16. Defendant Steven M. Paul ("Paul") served as Voyager's Chief Executive Officer ("CEO") from prior to the start of the class period until July 2018.

17. Defendant G. Andre Turenne ("Turenne") has served as Voyager's CEO since July 2018.

18. Defendant Jane Henderson ("Henderson") served as Voyager's Chief Financial Officer ("CFO") from prior to the start of the class period until June 2018.

19. Defendant Allison Dorval ("Dorval") served as Voyager's Vice President of Finance from June 2017 until November 2018 and as Voyager's Principal Financial Officer from June 2018 until November 2018, and has served as Voyager's CFO since November 2018.

20. Defendant Dinah Sah ("Sah") served as Voyager's Chief Scientific Officer from prior to the start of the Class Period until June 2019.

21. Defendant Omar Khwaja ("Khwaja") has served as Voyager's Chief Medical Officer since June 2019.

22. Defendants Paul, Turenne, Henderson, Dorval, Sah, and Khwaja are sometimes referred to herein as the "Individual Defendants."

23. The Individual Defendants possessed the power and authority to control the contents of Voyager's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Voyager's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Voyager, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

24. Voyager and the Individual Defendants are collectively referred to herein as "Defendants."

## SUBSTANTIVE ALLEGATIONS

### Background

25. Voyager, a clinical-stage gene therapy company, focuses on the development of treatments for patients suffering from severe neurological diseases. Included in the Company's preclinical programs is VY-HTT01 for Huntington's Disease. VY-HTT01 works by knocking

down HTT expression in neurons and astrocytes in the striatum and cortex (discrete regions in the brain that can be targeted with AAV gene therapy delivered directly into the brain), thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms.

26. On June 1, 2017, Voyager issued a press release announcing that it had selected VY-HTT01 as a lead clinical candidate for the treatment of Huntington's disease. The press release also indicated that, "[p]reclinical pharmacology and toxicology studies [were] underway with VY-HTT01 to support filing of an investigational new drug (IND) application in 2018."

27. In September 2020, Voyager submitted an IND application for VY-HTT01 for the treatment of Huntington's disease to the FDA.

**Materially False and Misleading Statements Issued During the Class Period**

28. The Class Period begins on June 1, 2017, when Voyager issued a press entitled, "Voyager Therapeutics Selects Lead Clinical Candidate For Huntington's Disease." The press release stated, in relevant part:

> [Voyager], a clinical-stage gene therapy company developing life-changing treatments for severe neurological diseases, today announced the selection of VY-HTT01, a clinical candidate for the treatment of Huntington's disease.
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> Preclinical pharmacology and toxicology studies are now underway with VY-HTT01 to support filing of an investigational new drug (IND) application in 2018.
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> "We systematically and thoroughly optimized the AAV capsid and transgene before selecting VY-HTT01 as the lead clinical candidate for Huntington's disease with scientists at Sanofi Genzyme, as part of our research alliance," said Dinah Sah, Ph.D., chief scientific officer at Voyager. "In preclinical models, a single administration of VY-HTT01 was well-tolerated and resulted in robust and widespread knockdown of HTT messenger RNA in disease-relevant regions of the non-human primate central nervous system. The extent of HTT mRNA suppression (greater than 50%) and high precision and efficiency of primary microRNA processing in these preclinical studies supported the selection of VY-HTT01 as our

> lead clinical candidate. Pre-IND safety studies are now underway in order to advance VY-HTT01 to Phase 1 clinical trials. In addition, as part of our candidate selection process, we carried out extensive optimization of the vector genome resulting in a configuration that provided excellent yield and genome integrity for manufacturing scale-up of VY-HTT01 using Voyager's baculovirus AAV manufacturing process in insect-derived cells."

29. On November 2, 2017, Voyager issued a press release announcing the Company's Q3 2017 financial results, and listed as one of Voyager's preclinical program highlights, in relevant part, "[p]reclinical pharmacology and toxicology studies are underway with VY-HTT01 to support the expected filing of an IND."

30. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q3 2017 results (the "Q3 2017 Earnings Call"). During the scripted portion of the Q3 2017 Earnings Call, Defendant Paul stated, in relevant part:

> It's helpful to remind ourselves that simply advancing programs into the clinic is not the goal. Advancing potentially best-in-class programs that have a high probability of success once in the clinic is the goal. And in our case, this starts with choosing and optimizing the AAV capsid, creating the right transgene, and most importantly optimizing delivery to the CNS.
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> At Voyager, we have taken a very systematic and rigorous approach to optimizing delivery as exemplified by our Parkinson's disease program. Our encouraging clinical results in Parkinson's disease are the direct result of optimizing gene delivery. We've, therefore, set a high bar as to how we select and identify our lead clinical candidates and then advance them towards the clinic.
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> In this regard, our ongoing efforts to optimize the capsid, transgene and delivery approaches applies to each of our preclinical programs: ALS, SOD1, Huntington's disease and Friedreich's ataxia. Now given recent and very exciting data and results with our novel AAV capsids and delivery strategies that have further enhanced gene delivery and CNS transduction in our preclinical studies, we plan to incorporate these new capsids and delivery approaches into our development plans going forward, particularly for the ALS SOD1 program.
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> As a result, while we're planning to file an IND ALS SOD1 by the end of this year or early next year, we now plan to delay the ALS IND and anticipate filing two INDs from the ALS Huntington's disease and Friedreich's ataxia programs in 2019. These new time lines in part are driven by the exciting recent data we've generated

> with our novel AAV capsids, some of which were presented last month at the ESGCT meeting in Berlin.

31. On March 14, 2018, Voyager filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2017 (the "2017 10-K"). In providing an overview of the Company's pipeline, the 2017 10-K stated, in relevant part:

> *Our Treatment Approach*
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> We believe that AAV gene therapy is an attractive approach to treating Huntington's disease. Since HTT mutations that cause Huntington's disease are toxic gain-of-function mutations, we believe that we can employ an AAV gene therapy approach designed to knock down expression of the HTT gene. In addition, the targeted cells for treatment primarily reside in discrete regions of the brain - the striatum and the cortex - that can be targeted with AAV gene therapy delivered directly into the brain. The mechanism of action of VY-HTT01 is knockdown of HTT expression in neurons in the striatum and cortex, thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms. We believe that we can use the same surgical approach for this program that has been used for VY-AADC delivery to the brain, allowing us to leverage prior clinical experience.
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> *Our Program Status*
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> Direct delivery of VY-HTT01 to the brain with a one-time administration could potentially slow or halt the progression of this uniformly fatal disease. Preclinical pharmacology and toxicology studies are now underway with VY-HTT01 to support filing of an IND application in 2019.

32. Appended to the 2017 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Paul and Henderson, attesting that, "the information contained in [the 2017 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

33. Corresponding with the 2017 10-K, Voyager issued a press release announcing the Company's Q4 2017 results and listing as one of Voyager's corporate goals, "[a]dvance multiple preclinical programs towards clinical trials through further vector optimization and exploration of additional routes of administration, to support filing two IND applications from the ALS SOD1, Huntington's disease, and Friedreich's ataxia programs during 2019."

34. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q4 2017 results (the "Q4 2017 Earnings Call"). During the scripted portion of the call, Defendant Paul stated, in relevant part, "We will continue to advance multiple preclinical programs towards clinical trials through further vector optimization and exploration of additional routes of administration leading to filing two IND applications from the ALS SOD1, Huntington's, or Friedreich's ataxia programs during 2019."

35. On May 10, 2018, Voyager issued a press release announcing the Company's Q1 2018 results and listing as one of Voyager's preclinical program highlights, in relevant part, "Voyager continues to advance multiple preclinical programs towards clinical trials through further vector optimization and exploration of additional routes of administration, to support filing two IND applications from its preclinical programs targeting a monogenic form of Amyotrophic Lateral Sclerosis (ALS) called SOD1, Huntington's disease, and Friedreich's ataxia programs."

36. On August 7, 2018, Voyager issued a press release announcing the Company's Q2 2018 results and listing as one of Voyager's preclinical program highlights:

> - During the second quarter, Voyager continued to advance its multiple preclinical programs towards clinical trials through further vector optimization and exploration of optimal routes of administration. [. . .] Additional new data at this year's ASGCT meeting included tolerability data in non-human primates for VY-HTT01 for Huntington's disease, along with previous data with VY-HTT01 that demonstrated a 54% suppression of huntingtin (HTT) mRNA in the non-human primate putamen after a single administration. Efforts to further optimize delivery for ALS and

> Huntington's disease programs are underway, and Voyager plans to provide results from these efforts at scientific conferences during the fourth quarter of this year.

37. On November 7, 2018, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2018 (the "Q3 2018 10-Q"). In providing an overview of the Company, the Q3 2018 10-Q stated, in relevant part, "[i]n 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application. [. . .] Further preclinical studies are underway with VY-HTT01 to support filing of an IND application in 2019."

38. Appended as an exhibit to the Q3 2018 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

39. On February 26, 2019, Voyager filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2018 (the "2018 10-K"). In providing an overview of Voyager's business, the 2018 10-K stated, in relevant part:

> In 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application. [. . .] Further preclinical studies are underway with VY-HTT01 which, if successful, will support a potential filing of an IND application in 2019.

40. Further, in providing an overview of the Company's pipeline, the 2018 10-K stated, in relevant part:

> *Our Treatment Approach*
>
> We believe that AAV gene therapy is an attractive approach to treating Huntington's disease. Since HTT mutations that cause Huntington's disease are toxic gain-of-function mutations, we believe that we can employ an AAV gene therapy approach designed to knock down expression of the HTT gene. In addition,

> the targeted cells for treatment primarily reside in discrete regions of the brain - the striatum and the cortex - that can be targeted with AAV gene therapy delivered directly into the brain. The mechanism of action of VY-HTT01 is knockdown of HTT expression in neurons in the striatum and cortex, thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms. We believe that we can use the same surgical approach for this program that has been used for VY-AADC delivery to the brain, allowing us to leverage prior clinical experience.
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> *Our Program Status*
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> Recent preclinical delivery studies have further optimized the dosing paradigm. [. . .] Further preclinical studies are underway with VY-HTT01 which, if successful, will support a potential filing of an IND application in 2019.

41. Appended as an exhibit to the 2018 10-K was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

42. Corresponding with the 2018 10-K, Voyager issued a press release announcing the Company's full year 2018 financial Results and listing as one of the Company's corporate goals, "[a]dvance VY-HTT01 for Huntington's disease and VY-SOD102 for ALS-SOD1 towards clinical trials. Preclinical pharmacology and toxicology studies are underway to support potential filings of IND applications for both programs later this year."

43. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q4 2018 results (the "Q4 2018 Earnings Call"). During the scripted portion of the Q4 2018 Earnings Call, Defendant Turenne stated, in relevant part:

> [a]nd for our Huntington's program, administration of VY-HTT01 in the putamen and thalamus of large animals resulted in significant reduction of HTT gene expression in deeper tissues and other layers of the brain. Preclinical toxicology studies are under way with a potential to file INDs for both of these programs later this year.

44. On May 7, 2019, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2019 (the "Q1 2019 10-Q"). In providing an overview of the Company, the Q1 2019 10-Q stated, in relevant part:

> In 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application. [. . .] Further preclinical studies are underway with VY-HTT01 which, if successful, are expected to support a potential filing of an IND application in 2019.

45. Appended as an exhibit to the Q1 2019 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

46. On August 9, 2019, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2019 (the "Q2 2019 10-Q"). In providing an overview of the Company, the Q2 2019 10-Q stated, in relevant part:

> In 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application. [. . .] Further preclinical studies are underway with VY-HTT01 which, if successful, are expected to support a potential filing of an IND application in 2019.

47. Appended as an exhibit to the Q2 2019 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

48. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q2 2019 results (the "Q2 2019 Earnings Call"). During the scripted portion of the Q2 2019 Earnings Call, Defendant Khwaja stated, in relevant part, "[w]e'll be focused on vetting the Huntington's disease program for a potential IND filing and entering into patients, while also prioritizing the identification and validation of new discovery targets and investing more

in our novel capsid world." Further, when asked a question regarding the "blocking and tackling need[ed] to be done on the Huntington's IND," Defendant Khwaja responded, in relevant part, "[s]o currently, I should say that we are focused on really vetting for potential IND filing if things line up toward the end of the year."

49. On November 6, 2019, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2019 (the "Q3 2019 10-Q"). In providing an overview of the Company, the Q3 2019 10-Q stated, in relevant part:

> In 2017, we selected VY-HTT01 as our clinical candidate for the treatment of Huntington's disease. Recent preclinical delivery studies have further optimized the dosing paradigm to support filing of a potential IND application.
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> We now anticipate, if current preclinical studies are successful, filing an investigational new drug (IND) application for VY-HTT01 for Huntington's disease during the first half of 2020. This will allow the IND application to include one-year data from preclinical studies instead of the previously planned six-month data. Leveraging our related clinical experience in Parkinson's disease, we still expect to screen and enroll the first patient in the planned clinical trial during 2020.

50. Appended as an exhibit to the Q3 2019 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

51. Corresponding with the Q3 2019 10-Q, Voyager issued a press release announcing the Company's Q3 2019 financial results, and listing as one of Voyager's corporate highlights:

- Voyager now anticipates, if current preclinical studies are successful, filing an investigational new drug (IND) application for VY-HTT01 for Huntington's disease during the first half of 2020. This will allow the IND application to include one-year data from preclinical studies instead of the previously planned six-month data. Leveraging its related clinical experience in Parkinson's disease, Voyager still expects to screen and enroll the first patient in the planned clinical trial during 2020.

52. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q3 2019 results (the "Q3 2019 Earnings Call"). During the scripted portion of the Q3 2019 Earnings Call, Defendant Turenne stated, in relevant part, "2020 is also expected to be an important year for Huntington's program as we anticipate filing an IND application and beginning screening and enrollment into the clinical trial." Also during the scripted portion of the Q3 2019 Earnings Call, Defendant Khwaja stated, in relevant part:

> We now expect filing an IND for VY-HTT01 for Huntington's disease during the first half of 2020. As the kinetics of Huntington knock-down appeared to be different in non-human primates than in rodents. We plan on submitting an IND application with final one-year data from our pre-clinical studies instead of the previously planned interim six months data. Our goal is to minimize the amount of time between IND acceptance and first patient dosed. We will be leveraging our related clinical experience in Parkinson's disease to achieve this. Activities toward site selection engagement have already begun and will continue to take place in the fourth quarter and the beginning of 2020.

53. On March 3, 2020, Voyager filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). In providing an overview of the Company's pipeline, the 2019 10-K stated, in relevant part:

> *Our Treatment Approach*
>
> We believe that AAV gene therapy is an attractive approach to treating Huntington's disease. Since HTT gene mutations that cause Huntington's disease are toxic gain-of-function mutations, we believe that we can employ an AAV gene therapy approach designed to knock down expression of the HTT gene. In addition, the targeted cells for treatment primarily reside in discrete regions of the brain - the striatum and the cortex - that can be targeted with AAV gene therapy delivered directly into the brain. The mechanism of action of VY-HTT01 is knockdown of HTT gene expression in neurons in the striatum and cortex, thereby reducing the level of toxicity associated with mutated protein in these brain regions, and slowing the progression of cognitive and motor symptoms. We believe that we can use the same surgical approach for this program that has been used for VY-AADC (NBIb-1817) delivery to the brain, allowing us to leverage prior clinical experience.
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*VY-HTT01 Program Status*

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VY-HTT01 is currently in preclinical IND-enabling studies. We are currently engaged in the ongoing conduct and review of preclinical studies for our Huntington's disease program, VY-HTT01, and expect to provide an update on the program in the second quarter of 2020, including plans to file an investigational new drug, or IND, application. We also plan to initiate a prospective observational study of patients with late prodromal and early manifest Huntington's disease in mid-2020. The longitudinal study will evaluate the clinical and biological evolution of peri-manifest Huntington's disease patients, including clinical, neuroimaging, molecular, and digital biomarker outcomes. Patients participating in the observational study may also be eligible for later enrollment in the VY-HTT01 Phase 1 clinical trial.

54. Appended as an exhibit to the 2019 10-K was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

55. Corresponding with the 2019 10-K, Voyager issued a press release announcing the Company's full year 2019 financial results and stating, in relevant part:

"In 2019, we took important steps toward our vision of establishing Voyager as the leader in neurological gene therapy, including forming our strategic collaboration with Neurocrine Biosciences, expanding our partnership with AbbVie, and further progressing our wholly-owned and partnered programs," said Andre Turenne, President and CEO of Voyager. "Turning to 2020, we are excited to continue this momentum across all programs. These initiatives include presenting longer-term data from the Parkinson's disease program, advancing our Huntington's disease program, and further leveraging our novel capsid research and expertise in vector engineering and delivery toward additional pipeline programs."

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**VY-HTT01 for Huntington's Disease**

- Voyager is currently engaged in the ongoing conduct and review of preclinical studies for its Huntington's disease program, VY-HTT01, and expects to provide an update on the program in the second quarter of 2020, including plans to file an IND application.

- Voyager also plans to initiate a prospective observational study of patients with late prodromal and early manifest Huntington's disease in mid-2020.

> The longitudinal study will evaluate the clinical and biological evolution of peri-manifest Huntington's disease patients, including clinical, neuroimaging, molecular, and digital biomarker outcomes. Patients participating in the observational study may also be eligible for later enrollment in the VY-HTT01 Phase 1 clinical trial.

56. That same day, Voyager hosted an earnings call with investors and analysts to discuss the Company's Q4 2019 results (the "Q4 2019 Earnings Call"). When asked "what remain[ed] outstanding ahead of the Huntington's IND," Defendant Khwaja responded, in relevant part:

> [F]or the IND filing, we have a lot of bioanalytics which are still coming in from our GLP studies which are IND-enabling. And as we guided on our last call, we are running the study out to 53 weeks. So that's an increased number of samples. And then we're looking at a number of bioanalytics from including the vector genomes, but also the microRNA itself mRNA and protein in multiple tissues and also brain regions. So at the moment, we're really going through that data and reviewing it and analyzing it. So that's the sort of piece that lies between this time point and the IND. The observational study is not gated on the timing of the IND. And so that is in active study set up now and we anticipate that being active by midyear with first patients coming into that.

Further, when asked a question regarding the "preclinical data sets that [Voyager was] still generating for [the] Huntington's disease IND filing," Defendant Khwaja responded, in relevant part:

> So, we're really at the moment in the phase of completing analyzing bio-analytics from the large number of samples that have been taken during the GLP studies up to 53 weeks. So, it's a significant number of animals and a significant number of tissues that we're analyzing as well as brain regions. So, that's really where the team's activity is predominantly on the sort of -- for the IND filing.
>
> The second are the preparations for the Phase 1 as well as the observational study which are now very advanced stems and so there's a lot of team activity on that. We would anticipate presenting our non-human primate long-term data from our GLP studies at an appropriate time, but the predominant focus right now is on the IND preparation and readiness for dosing a patient in Phase 1.

57. On May 6, 2020, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the

"Q1 2020 10-Q"). In providing an overview of the Company, the Q1 2020 10-Q stated, in relevant part:

> We are currently engaged in the ongoing conduct and review of preclinical studies for our Huntington's disease program, VY-HTT01. Pending this review, we are planning for the potential initiation of both a first in human Phase 1 study of VY-HTT01 and a prospective observational study of patients with late prodromal and early manifest Huntington's disease. We anticipate providing an update on the program in mid-2020.

58. Appended as an exhibit to the Q1 2020 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

59. Corresponding with the Q1 2020 10-Q, Voyager issued a press release announcing the Company's Q1 2020 results and stating, in relevant part:

> **VY-HTT01 for Huntington's Disease**
>
> - Voyager is currently engaged in the ongoing conduct and review of preclinical studies for its Huntington's disease program, VY-HTT01. Pending this review, Voyager is planning for the potential initiation of both a first-in-human Phase 1 study of VY-HTT01 and a prospective observational study of patients with late prodromal and early manifest Huntington's disease. Voyager anticipates providing an update on the program in mid-2020.

60. On August 10, 2020, Voyager filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "Q2 2020 10-Q"). In providing an overview of the Company, the Q2 2020 10-Q stated, in relevant part, "[w]e recently completed IND-enabling preclinical studies and are in the process of finalizing an IND application for VY-HTT01 for the treatment of Huntington's disease which we expect to file with the FDA during the second half of 2020." Further, the Q2 2020 10-Q stated, in relevant part, "[f]ollowing clearance of the IND by the FDA, we expect to begin the first-in-human clinical trial of VY-HTT01 in Huntington's disease patients."

61. Appended as an exhibit to the Q2 2020 10-Q was substantively the same SOX certification as referenced in ¶ 32, signed by Defendants Turenne and Dorval.

62. Corresponding with the Q2 2020 10-Q, Voyager issued a press release announcing the Company's second quarter 2020 financial results and listing as one of Voyager's corporate updates, "Voyager recently completed IND-enabling preclinical studies and is finalizing an IND application for VY-HTT01 in Huntington's disease, which it expects to file with the U.S. Food and Drug Administration (FDA) in the second half of 2020."

63. The statements referenced in ¶¶ 28-62 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's VY-HTT01 IND submission to the FDA lacked key information regarding certain CMC matters, including, *inter alia*, drug-device compatibility and drug substance and product characterization; (ii) the Company's IND submission for VY-HTT01 was therefore deficient; (iii) the Company had thus materially overstated the likelihood of FDA approval for VY-HTT01 based on the IND submission; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

**The Truth Begins to Emerge**

64. On October 12, 2020, Voyager issued a press release disclosing that it "has received feedback from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug (IND) submission for VY-HTT01 for the treatment of Huntington's disease." Specifically, Voyager advised investors that it "has been notified that the IND was placed on clinical hold pending the resolution of certain chemistry, manufacturing and controls (CMC) matters."

65. Despite the negative news, the stock continued to trade at artificially inflated prices as a result of the Company's continuing misstatements. For example, the October 12, 2020 press release also stated, in relevant part, "[t]he Company expects to receive specific feedback from the FDA on these matters within 30 days and plans to work closely with the agency to resolve them and promptly begin the clinical evaluation of VY-HTT01."

66. Then, on November 9, 2020, Voyager issued a press release announcing the Company's third quarter 2020 financial results and corporate updates. In the press release, the Company disclosed that, with respect to its IND application for VY-HTT01, "the FDA ha[d] provided clarity regarding the additional information it is requesting pursuant to our IND filing." Specifically, the press release stated, in relevant part:

- In September 2020, Voyager submitted an IND application for VY-HTT01 in Huntington's disease, and in October, Voyager was notified that the IND had been placed on clinical hold pending the resolution of certain CMC information requests. Voyager recently received written feedback from the FDA requesting additional information on specific CMC topics, including drug-device compatibility and drug substance and product characterization. Voyager plans to work closely with the agency to resolve the additional information request in a timely manner.

67. On this news, Voyager's stock price fell $2.60 per share, or 23.21%, to close at $8.60 per share on November 10, 2020.

68. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

## PLAINTIFF'S CLASS ACTION ALLEGATIONS

69. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Voyager securities during the Class Period (the "Class"); and were damaged upon the

revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

70. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Voyager securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Voyager or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

71. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

72. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

73. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Voyager;

- whether the Individual Defendants caused Voyager to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Voyager securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

74. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

75. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Voyager securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Voyager securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

76. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

77. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

## COUNT I

**(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)**

78. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

79. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

80. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Voyager securities; and

(iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Voyager securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

81. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Voyager securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Voyager's finances and business prospects.

82. By virtue of their positions at Voyager, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

83. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Voyager, the Individual Defendants had knowledge of the details of Voyager's internal affairs.

84. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Voyager. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Voyager's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Voyager securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Voyager's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Voyager securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

85. During the Class Period, Voyager securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Voyager securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Voyager securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Voyager securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

86. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

87. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

## COUNT II

**(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)**

88. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

89. During the Class Period, the Individual Defendants participated in the operation and management of Voyager, and conducted and participated, directly and indirectly, in the conduct of Voyager's business affairs. Because of their senior positions, they knew the adverse non-public information about Voyager's misstatement of income and expenses and false financial statements.

90. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Voyager's financial condition and results of operations, and to correct promptly any public statements issued by Voyager which had become materially false or misleading.

91. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Voyager disseminated in the marketplace during the Class Period concerning Voyager's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Voyager to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Voyager within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Voyager securities.

92. Each of the Individual Defendants, therefore, acted as a controlling person of Voyager. By reason of their senior management positions and/or being directors of Voyager, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Voyager to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Voyager and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

93. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Voyager.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: January 22, 2021

Respectfully submitted,

**POMERANTZ LLP**

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***Additional Counsel for Plaintiff***

**CERTIFICATION PURSUANT**
**TO FEDERAL SECURITIES LAWS**

1. I, Selwyn Karp, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against Voyager Therapeutics, Inc. ("Voyager" or the "Company") and authorize the filing of a comparable complaint on my behalf.

3. I did not purchase or acquire Voyager securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or otherwise acquired Voyager securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. To the best of my current knowledge, the attached sheet lists all of my transactions in Voyager securities during the Class Period as specified in the Complaint.

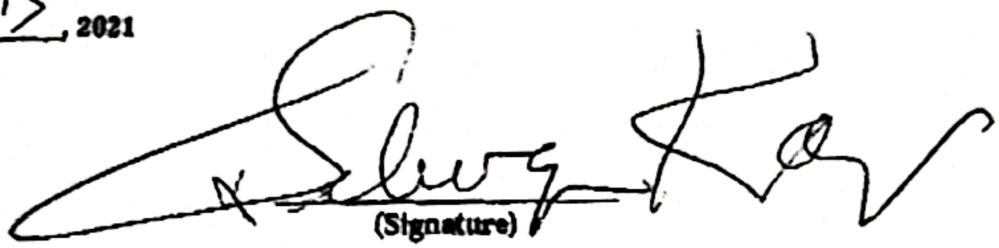
6. During the three-year period preceding the date on which this Certification is signed, I have served or sought to serve as a representative party on behalf of a class under the federal securities laws in the following proceedings:

- *Karp v. First Connecticut Bancorp, Inc. et al*, No. 1:18-cv-02496 (D. Md. Aug 14, 2018);
- *Karp v. SI Financial Group, Inc. et al*, No. 3:19-cv-00199 (D. Conn. Feb 08, 2019);
- *Karp v. FedEx Corporation et al,* Docket No. 1:19-cv-06183 (S.D.N.Y. Jul 02, 2019); and
- *In re Diebold Nixdorf, Inc. Securities Litigation*., No. 1:19-cv-06180 (S.D.N.Y. Jul 02, 2019).

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Executed: January 13, 2021
(Date)



(Signature)

Selwyn Karp
(Type or Print Name)

**Voyager Therapeutics, Inc. (VYGR)** **Karp, Selwyn**

**List of Purchases and Sales**

| Transaction Type | Date | Number of Shares/Unit | Price Per Share/Unit |
|---|---|---|---|
| Purchase | 4/20/2018 | 2,000 | $18.8010 |
| Purchase | 5/30/2018 | 1,000 | $20.3620 |
| Purchase | 5/30/2018 | 500 | $20.4140 |